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THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

STEVE ELLIS, et al.,

Plaintiffs,

v.

STEVEN P. BRADBURY, et al.,

Defendants,

and

BAYER CROPSCIENCE LP, SYNGENTA CROP PROTECTION, LLC, VALENT U.S.A. CORPORATION, AND CROPLIFE AMERICA,

Defendant-Intervenors.

Case No. 3:13-cv-01266-MMC

DEFENDANT-INTERVENORS' REPLY IN SUPPORT OF THEIR MOTION TO DISMISS AND FOR JUDGMENT ON THE PLEADINGS

(Fed. R. Civ. P. 12)
Date: January 24, 2014
Time: 9:00 a.m.
Place: Courtroom 7, 19th Floor

Honorable Maxine M. Chesney

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I. INTRODUCTION AND SUMMARY

Plaintiffs' Opposition further confirms that they have filed suit at the wrong time and, for some claims, in the wrong court. Much of the Opposition addresses a straw man under which judicial review would be barred until "2021 or 2022" unless Plaintiffs are permitted to circumvent basic principles of judicial review and statutory procedures designed to protect national environmental and agricultural interests. The record demonstrates Plaintiffs' ability to obtain a prompt EPA final decision on a properly-presented claim. It is solely due to Plaintiffs' piecemeal, duplicative, and dilatory approach that all but one of their claims are either still pending before EPA for final decision, or were never presented to EPA in the first instance. Plaintiffs' claims are being heard through the EPA process they initiated and they should not be permitted to bypass those administrative procedures. While conceding that FIFRA § 6 provides the exclusive means to suspend or cancel a registration, Plaintiffs insist on seeking the same relief outside that process, and ask the Court to negate the statutory language that squarely plants jurisdiction for such claims only in an action for review of an EPA "refusal . . . to cancel or suspend a registration."

Plaintiffs' claims are being addressed, and should be addressed, in the timely and orderly manner provided under FIFRA and the ESA, with an opportunity for appropriate judicial review of EPA's final resolution of the issues, in the correct court, with the benefit of a complete record and EPA's expert analysis. As stated in Intervenors' Motion [Dkt. 74], with the possible exception of their merits challenge to EPA's decision not to suspend clothianidin,[1] Plaintiffs' remaining Claims (3-9, 13-14, and parts of Claim 1)[2] should be dismissed for lack of jurisdiction, or alternatively for failure to state a claim.

II. ARGUMENT

A. Plaintiffs Have Not Demonstrated Jurisdiction for Their Claims

1. The Court of Appeals Has Exclusive Jurisdiction Over Claims 5 and 13

While conceding that EPA's solicitation of comment on their clothianidin Petition was a "hearing" vesting exclusive jurisdiction over EPA's final decision in the court of appeals, Plaintiffs

[1] Jurisdiction over this decision arguably resides in the court of appeals. Mot. at 8 n.7.

[2] Plaintiffs voluntarily dismissed, with prejudice, four claims (2, 10, 11, and 12). [Dkt. 81].

suggest that EPA did not thereby solicit comment on "whether to act" on the Claims *in* the Petition and therefore this Court simultaneously has jurisdiction to review those Claims. Opp. at 13 [Dkt. 84].[3] To the contrary, judicial review of EPA's future decision on the Petition cannot be separated from review of the claims in the Petition, and Plaintiffs' theory would impermissibly permit simultaneous jurisdiction in district court and the court of appeals over the same claims. *See* Mot. at 7.[4]

2. Claims 5-6 and 13-14 Are Still Pending Before EPA and Are Not Ripe

Plaintiffs invite the Court to ignore that their Claims are now pending before EPA, asserting that EPA's decision on the Petition will have "no bearing on" their claims and is "irrelevant," and that judicial intervention would not "inappropriately interfere with further administrative action." Opp. at 10-12. Not so. Plaintiffs themselves put Claims 5 and 13 before EPA in the Petition, and Claims 6 and 14 in the Comment Letter, and EPA is considering these Claims now. Judicial review of matters still being considered by the agency is strongly disfavored, as it may waste judicial resources, and encroaches on the agency's role. Mot. at 12-13 (citing Ninth Circuit cases); *see also Bellsouth Corp. v FCC*, 17 F.3d 1487, 1489 (D.C. Cir. 1994) (recognizing "the rule against simultaneous judicial review and agency reconsideration," which avoids "wast[ing] judicial resources"); *Wade v. FCC*, 986 F.2d 1433, 1434 (D.C. Cir. 1993) ("So long as a request for agency reconsideration remains pending, . . . attempt to seek judicial review must be dismissed as 'incurably premature'"). Plaintiffs do not deny that EPA's forthcoming decisions could moot their Claims. *See, e.g.*, *Ukiah Valley Med. Ctr. v. FTC,* 911 F.2d 261, 264 n.1 (9th Cir. 1990) (agency action not final or ripe where pending agency determination could moot case). EPA's decision on Plaintiffs' Claims will not be "irrelevant," as EPA is the expert agency charged with deciding in the first instance whether the facts warrant initiation of cancellation or suspension

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[3] Plaintiffs also assert that the Complaint is "broader" than the Petition as it identifies more studies as alleged conditions of registration and cites a recent scientific study. Opp. at 14. Plaintiffs' decision to present these allegations in the Complaint, and not a supplemental Petition, does not affect the court of appeals' exclusive jurisdiction. *See Am. Bird Conservancy v. FCC*, 545 F.3d 1190, 1194 (9th Cir. 2008) ("plaintiff may not escape an exclusive avenue of judicial review through artful pleading").

[4] *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 745 (1985)(any ambiguity resolved in favor of court of appeals jurisdiction); *Ruud v. Dep't of Labor*, 347 F.3d 1086, 1090 (9th Cir. 2003) (jurisdiction to be interpreted to "avoid[] inconsistency and conflicts" and ensure "efficient resolution" of cases); *Envtl. Def. Fund v. EPA*, 485 F.2d 780, 783 (D.C. Cir. 1973) (purpose of FIFRA § 16's allocation of jurisdiction "would be defeated if" an EPA order were "to be litigated in several proceedings").

proceedings under § 6. Hearing the Claims now would plainly "interfere with the system that Congress specified" under FIFRA. *Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 735-36 (1998).[5]

Thus, of the three traditional ripeness factors, two plainly weigh against conducting judicial review now: (1) "judicial intervention would inappropriately interfere with further administrative action" and (2) the Court "would benefit from further factual development of the issues presented." *Id.* at 733. Plaintiffs cite the third factor, undue hardship from delayed judicial review, but their assertions ring hollow.[6] Despite their allegations of bee impacts starting in "2003-2004," Am. Compl. ¶ 57, Plaintiffs waited eight years, until March 2012, to submit the Petition, and then waited another eight months after EPA's Partial Decision before filing this action. The notion that Plaintiffs will suffer undue hardship if EPA is allowed to complete its review of claims Plaintiffs themselves presented to the Agency does not withstand scrutiny. Claims 5-6 and 13-14 should be dismissed as unripe.

3. Plaintiffs' Blatant Attempt to Circumvent FIFRA § 6 Should Be Rejected

a. Applying § 16(a) Will Not Unreasonably Restrict Judicial Review

Plaintiffs misrepresent Intervenors' position as requiring a petition before "any judicial review of *any* EPA final agency action." Opp. at 3 (emphasis added). Plaintiffs spend pages attacking a "far-fetched scheme whereby harmed parties could rarely, if ever, seek judicial review." Opp. at 1; *see also id.* at 3 (EPA would be "shielded from any judicial review"). This "scheme" is a straw-man invented by Plaintiffs to mask their attempt to circumvent the statute and Ninth Circuit precedent.

Intervenors' actual position is much narrower: Plaintiffs may not bypass § 6 by going directly to court to suspend or cancel an existing registration. This conclusion is dictated by the plain language of the statute, and has been adopted by every court to have considered the question. *See* Mot. at 8-12.

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[5] Plaintiffs also characterize their claims as akin to "procedural challenge[s] under NEPA." Opp. at 9-10. The cases they cite, including Plaintiffs' misleading application of *Ohio Forestry Ass'n*, arise from the uniquely procedural nature of NEPA and have no bearing on FIFRA or its procedures, which differ "from the NEPA procedures in several important aspects." *Douglas Cnty. v. Babbitt*, 48 F.3d 1495, 1502 (9th Cir. 1995); *see also Earth Island Inst. v. U.S. Forest Serv.*, 697 F.3d 1010, 1019 (9th Cir. 2012) ("NEPA sets forth procedural (rather than substantive) requirements for agency decision-makers.").

[6] Plaintiffs have submitted numerous declarations from beekeepers repeating the unscientific bee health allegations in the Complaint. These declarations do not address any issue raised by Intervenors' Motion, and should be disregarded by the Court.

Plaintiffs ask this Court to ignore the first half of the operative jurisdictional provision in § 16(a), which limits jurisdiction over challenges to existing registrations to review of "the refusal of the Administrator to cancel or suspend a registration." 7 U.S.C. § 136n(a).

While § 6 is the sole mechanism to cancel or suspend a registration, there are many "other" final EPA actions under FIFRA subject to immediate district court review under the second half of § 16(a). The very cases cited by Plaintiffs illustrate this point.[7] *See, e.g.*, *Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131, 1141 (D.C. Cir. 2010) (district court review of EPA exercise of "misbranding" authority); *AMVAC v. EPA*, 653 F.2d 1260, 1265 (9th Cir. 1981) (district court review of EPA decision not to hold a hearing); *Envtl. Def. Fund v. Blum*, 458 F. Supp. 650 (D.D.C. 1978) (district court review of EPA decision to invoke statutory exemption from registration requirement for federal and state agencies).

Similarly, EPA's final decision at the end of Registration Review (underway for both clothianidin and thiamethoxam) also may be subject to judicial review without a petition. A plaintiff may seek to vacate the Registration Review decision, and a remand for further consideration, without seeking the cancellation or *vacatur* of any individual product registration. Decisions made in the "reregistration" process (predecessor to Registration Review), such as a final Reregistration Eligibility Decision ("RED") or Interim RED ("IRED"), also could be subject to judicial review. Again, such a challenge would not seek cancellation of an existing product registration outside of the § 6 process. 7 U.S.C. § 136a-1(g)(2)(A), (D); *United Farm Workers v. EPA*, 592 F.3d 1080 (9th Cir. 2010) (reviewing IRED). But the statute expressly *bars* the cancellation of any specific registration, even as a result of Registration Review, except through the cancellation process of § 6 — further confirming § 6 as the exclusive means for cancelling a registration. *See* 7 U.S.C. 136a(g) ("No registration shall be canceled as a result of the registration review process unless [EPA] follows the procedures and substantive requirements of section 6."). In contrast to a Registration Review decision or RED, rules of general applicability, a registration is an individual license — a property right — and Congress established numerous provisions in FIFRA to

[7] None of the Ninth Circuit cases cited by Plaintiffs address judicial suspension or cancellation of a registration. *See, e.g.*, Opp. at 7 (citing *Wash. Toxics Coal. v. EPA*, 413 F.3d 1024, 1033-34 (9th Cir. 2005) (approving interim injunctive measures on a limited local basis, but not cancelling or suspending the registrations); *Or. Envtl. Council v. Kunzman*, 714 F.2d 901 (9th Cir. 1983) (not a challenge to existing registration); *Sierra Club v. Peterson*, 705 F.2d 1475 (9th Cir. 1983) (same)).

protect a registrant's property interest in that license. *See, e.g.*, 7 U.S.C. §§ 136d, 136a(g).

b. Plaintiffs Will Have Their Day in Court

For these and other reasons, Plaintiffs' contention that awaiting a final EPA decision on their claims would bar any judicial review of EPA activities until "2020 or 2021" is a fiction. Opp. at 12. Plaintiffs' actions further illustrate this. Plaintiffs obtained a very prompt and thorough final EPA decision on their allegations of an "imminent hazard" to bees from clothianidin, and no party has moved to dismiss Plaintiffs' challenge to that EPA decision, or denied that Claim's ripeness for review in the appropriate court. *See* Mot. at 8 n.7. Plaintiffs also demonstrated their ability to navigate the petition process when, in December 2010, Plaintiff Beyond Pesticides formally requested that EPA suspend all clothianidin use based on the same allegation now presented as Claim 5 — *i.e.*, that a 2003 condition of registration requiring a pollinator "field study" was not met. EPA issued a prompt final decision in February 2011, in which EPA explained that the pollinator field study *was* timely completed and accepted as satisfying the condition of registration. *See* Am. Compl. ¶¶ 5, 81. That Plaintiffs chose to wait eight years before presenting their allegations to EPA is no reason to assume that following the orderly process of § 6 and § 16(a) would deny timely judicial review. Any difficulties Plaintiffs are encountering in perfecting their claims for judicial review are attributable to their own conduct.

c. Plaintiffs Cannot Through "Artful Pleading" Effectively Cancel Over 100 Registrations, Evading the Protections of FIFRA § 6

Plaintiffs concede that "Congress intended EPA to use § 6 cancellation to remove products from the market," that "registrants are entitled to the cancellation procedures outlined in § 6, and [that] EPA is required to follow those procedures when a product is not eligible for reregistration." Opp. at 9. Plaintiffs admit that the case law "states that plaintiffs *solely* seeking cancellation must go through FIFRA's cancellation process." *Id.* (emphasis added). They attempt to distinguish their claims as "not *merely* seek[ing] cancellation" but also other remedies, and assert they are "not limited to FIFRA § 6 *for those other remedies*." *Id.* (emphases added). Specifically, Plaintiffs say they seek "declaratory relief, as well as vacatur of the registrations and/or an injunction halting the pesticides' uses." Opp. at 6; *id.* at 6-7 n.5 (explaining that the declaratory relief sought is a "declaration that the registrations . . . are illegal" with a Court order to "vacate them" and "suspend use" of the products). From their own descriptions, it

could not be clearer that the relief Plaintiffs seek would effectively suspend or cancel the challenged registrations. Plaintiffs may not circumvent, through artful pleading, the process established by the statute as the exclusive cancellation and suspension mechanism for an existing registration.

Plaintiffs ask the Court to ignore the Ninth Circuit's reasoning in *Merrell v. Thomas*, 807 F.2d 776 (9th Cir. 1986), as "dicta." But the Court was only able to reach its decision that NEPA procedures do not apply to FIFRA registration actions based on its comprehensive review and analysis of the legislative intent expressed in the FIFRA scheme, and its conclusion that "FIFRA provides for substantial public participation only after a pesticide is registered," in the form of a petition to cancel, followed by judicial review. *Merrell*, 807 F.2d at 782. The Ninth Circuit's definitive interpretation of FIFRA cannot simply be ignored. As the *Merrell* Court observed, many other "[e]nvironmental organizations have acted under these notice and review provisions to challenge EPA *refusals* to cancel or suspend pesticide registrations," and this process has worked since the 1970s. *Id.* (emphasis added). Plaintiffs must first petition EPA before effectively seeking cancellation in court. Accordingly, Claims 3-9 and 13-14, and parts of Claim 1, should be dismissed for lack of subject matter jurisdiction.

4. Plaintiffs Failed to Provide Sufficient Notice of Their ESA Claims

Plaintiffs have not demonstrated, and cannot demonstrate, that their Notice of Intent ("NOI") included their ESA § 9 "take" claims or their claims regarding the 17 registrations not identified in the NOI. *See* Mot. at 15-16. Plaintiffs erroneously assert that the ESA notice requirement is less "exacting" than that in other statutes, like the Clean Water Act ("CWA"), and that compliance is "evaluated in a pragmatic manner." Opp. to EPA at 32-33. To the contrary, the Ninth Circuit has made clear that: "A failure to *strictly comply* with the notice requirement acts as an absolute bar to bringing suit under the ESA" and that "citizen suit notice requirements cannot be avoided by employing a flexible or pragmatic construction." *Sw. Ctr. for Biological Diversity v. U.S. Bureau of Reclam.*, 143 F.3d 515, 520 (9th Cir. 1998) (emphasis added) (citing *Hallstrom v. Tillamook Cty.*, 493 U.S. 20, 26-28 (1989)). The NOI does not even mention an ESA "take" claim, or the 17 registrations cited in the Complaint that Plaintiffs admit post-date the NOI. Opp. to EPA at 32-33. These ESA claims must be dismissed.[8]

[8] Plaintiffs cite *Marbled Murrelet v. Babbitt*, 83 F.3d 1068 (9th Cir. 1996), but the case refutes their argument. *See* Opp. to EPA at 32 n.29. The NOI in that case specifically raised ESA § 9 "take" claims.

5. Plaintiffs Lack Standing to Bring Their ESA Claims

Plaintiffs' Opposition and declarations do not cure their failure to plead facts sufficient to support Article III standing for the ESA claims. Much of the declarations are simply irrelevant, as they address honeybees, birds, and other non-ESA-listed species. The few that relate to ESA-listed species fall short of what is required. Of the 22 declarations, only five even identify an ESA-listed species that (i) could possibly trigger ESA consultation, *and* (ii) was at least mentioned in Plaintiffs' NOI.[9] The Court should summarily disregard the 17 remaining declarations, seven of which reference only ESA-listed species not included in the NOI or Complaint,[10] and 10 of which fail to mention an interest in any ESA-listed species.[11] The five remaining declarations (Zaber, Markham, Crouch, Hinerfeld, and Owens) identify a total of six ESA-listed insect species.

Thus, as an initial matter, Plaintiffs have not come close to alleging facts to support standing to seek a nationwide injunction for ESA consultation on all of the species referenced in the NOI, Complaint, and declarations. Even if the other elements of standing were met, at most Plaintiffs' ESA claims and requested relief would be confined to claims relating to the six listed insect species and their specific limited habitats.[12] *Ctr. for Biological Diversity v. EPA ("CBD v. EPA")*, Case No. 11-cv-00293-JCS, 2013 U.S. Dist. LEXIS 57436, at *40 (N.D. Cal. Apr. 22, 2013).

Plaintiffs' reliance on *Natural Res. Def. Council v. Sw. Marine, Inc.*, 236 F.3d 985 (9th Cir. 2000), is equally misplaced. Opp. to EPA at 33. There, a CWA NOI was found sufficient for a claim that arose before, and *was addressed* in, the NOI. The court did not find that the NOI sufficed to cover activities not identified in it, or that arose after it. 236 F.3d at 996-97. Similarly, in *Cmty. Ass'n for Restoration of the Env't v. Henry Bosma Dairy*, none of the un-noticed activities post-dated the NOI. 305 F.3d 943, 948, 951-52 (9th Cir. 2002).

[9] Those six species are the American burying beetle (Crouch Decl.), Mitchell's satyr butterfly (Crouch Decl.), Fender's blue butterfly (Hinerfeld Decl.), Karner blue butterfly (Markham and Zaber Decls.), Quino checkerspot butterfly (Owens Decl.), and Hine's emerald dragonfly (Zaber Decl.). None of the other species in these five declarations were referenced in the NOI.

[10] *See* Declarations of Ferrato, Goller, Hess, Horowitz, Landers, Melampy, and Vosberg. The failure to identify species in the NOI is fatal to Plaintiffs' corresponding claims. *Sw. Ctr.*, 143 F.3d at 520-22 (dismissed because NOI failed to identify specific species or habitat at issue).

[11] *See* Declarations of Carman, Chieffe, Cox, Doan, Ellis, Feldman, Kimbrell, Miles, Rhodes, and Theobald.

[12] None of the six insects has anything approaching a nationwide range. For example, the Species Profiles on U.S. Fish and Wildlife Service's website, which designates the localities in which each listed species is "known or believed to occur," show that Fender's blue butterfly is known to exist only

In any event, the five declarations that identify these six ESA-listed insects still fail to satisfy standing requirements. Each links the declarant to a species and broadly alleges that the species is harmed by the two challenged pesticides.[13] Plaintiffs claim that these facts establish standing for the ESA claims and seek to distinguish this case from *CBD v. EPA*. Plaintiffs are wrong on both counts. Plaintiffs ignore a core requirement of Judge Spero's analysis — a causal connection between the identified species and *a challenged EPA registration action*. *CBD v. EPA*, 2013 U.S. Dist. LEXIS 57436, at *40 ("each pesticide corresponds to *an individual agency affirmative act* which triggers the EPA's duty to consult with the Services") (emphasis added). None of Plaintiffs' declarants identify which of the over 100 EPA registration activities listed in the Complaint Appendices are causing them harm. Instead, they broadly attack EPA's past and continuing registration of the two pesticides with, at most, only general references to application to corn, soybean, and other unnamed crops.[14]

Plaintiffs seek an injunction requiring ESA consultation on *all* the identified EPA activities, but have failed to link even *one* to their alleged injuries. Treating the dozens of EPA registrations in the Complaint as a single exercise of agency authority that has purportedly caused Plaintiffs' injuries obscures the distinct nature of each EPA approval. Plaintiffs' own Complaint demonstrates that each EPA action is directed toward a distinct *use* for the pesticide product in question — for flowers and shrubs, particular crops, bedbugs, wood treatment, commercial property use, and so on —— and that the uses are diverse. *See, e.g.*, Am. Compl., App. A at 5 (bedbugs); *id.* App. B at 4 ("for

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in five counties in Oregon, and the Quino checkerspot butterfly in five California counties, with the other four species limited to four to 10 states. *See* www.fws.gov/endangered (visited Dec. 4, 2013).

[13] Only the Zaber, Markham, and Crouch declarations even hint at how the identified ESA-listed species are exposed to the pesticides, referencing corn and/or soybean fields in the species habitat. The Hinerfeld and Owens statements make no attempt to link the ESA-listed species to known or alleged pesticide use in the identified geographic area. They instead just broadly allege that the ESA-listed species are jeopardized by neonicotinoids. *See, e.g.*, Hinerfeld Decl. ¶ 19. And three declarants (Crouch, Hinerfeld, Markham) have never even seen the identified species, instead claiming a desire to do so in the future, thus stretching Article III injury in fact past its limit. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 564 (1992).

[14] *See, e.g.*, Crouch Decl. ¶ 5; Hinerfeld Decl. ¶ 21; Markham Decl. ¶ 7; Owens Decl. ¶ 14; Zaber Decl. ¶ 9.

manufacturing purposes only"), 7 ("structure-invading ants"). For example, there is no reason to assume that indoor uses (such as clothianidin use on bedbugs) could affect endangered species.

The plaintiffs in *CBD v. EPA* could not establish "standing in gross" for multiple species and pesticides with no specific facts linking them. *CBD v. EPA*, 2013 U.S. Dist. LEXIS 57436, at *39-40 (citing *Lewis v. Casey*, 518 U.S. 343, 358 n.6 (1996)); *see also CBD v. EPA*, Case No. 11-cv-00293-JCS, 2013 U.S. Dist. LEXIS 169015, at *18-22 (N.D. Cal. Nov. 25, 2013) (reiterating that plaintiffs must identify an affirmative agency act and show standing). So too here, Plaintiffs seek to bypass the elements of standing and demand an injunction against EPA implicating dozens of diverse EPA activities, without pleading facts linking any individual EPA activities to their alleged ESA injuries. *CBD v. EPA*, 2013 U.S. Dist. LEXIS 57436, at *40. Without even an *allegation* that a specific EPA action is tied to the species and interests that Plaintiffs assert, Plaintiffs have failed to demonstrate standing for their ESA claims, and the claims should be dismissed.

B. Failure to State a Claim Upon Which Relief May Be Granted

1. Plaintiffs Provide No Response on Issue Exhaustion (Claims 3-4, 7-9)

Claims 3-4 and 7-9 were omitted from Plaintiffs' multiple EPA submissions, warranting dismissal of the claims for lack of "issue exhaustion." Mot. at 16. Issue exhaustion is separate and distinct from exhaustion of administrative remedies, and can apply "even in the absence of a statute or regulation." *Sims v. Apfel*, 530 U.S. 103, 108 (2000). Plaintiffs ignore this argument, and instead address exhaustion of administrative remedies. Thus, the Court may treat the issue as unopposed.[15]

Under the doctrine of "issue exhaustion" a party cannot present arguments for the first time in court that were not raised during an administrative process. Mot. at 16-17. Plaintiffs here repeatedly invoked the administrative process (notwithstanding Plaintiffs' position that this was not legally required). Thus, they had multiple opportunities to present their claims to EPA. But Plaintiffs elected to withhold some of their claims from EPA, thereby depriving this Court of the benefit of EPA's

[15] *See, e.g.*, *Shakur v. Schriro*, 514 F.3d 878, 892 (9th Cir. 2008) (claim abandoned where not raised in opposition to summary judgment motion); *Rosenfeld v. Dep't of Justice*, 903 F. Supp. 2d 859, 869 (N.D. Cal. 2012) ("[F]ailure to respond in an opposition brief to an argument put forward in an opening brief constitutes waiver or abandonment.") (citations omitted).

analysis and a more complete record, and depriving EPA of the chance to address the claims in the first instance. *See* Mot. at 17. Plaintiffs offer no explanation for their conduct, and no reason to depart from the well-established rule. Claims 3-4 and 7-9 should be dismissed.

2. Plaintiffs' Notice Allegations (Claims 3-4) Fail to State a Claim

a. Plaintiffs Do Not Contest That the Statute of Limitations Bars Their Challenges to 30 Registrations Issued Before March 21, 2007

Plaintiffs do not contest that any claim based on a notice allegedly required to be issued before March 21, 2007, is barred by the six-year statute of limitations. *See* Mot. at 17. Thus, at a minimum, Plaintiffs' challenges to the 30 registrations issued before March 21, 2007 should be dismissed. *See* Mot. at 17; Am. Compl. ¶¶ 112, 117; *Ramirez v. Ghilotti Bros.*, No. C 12-04590 CRB, 2013 U.S. Dist. LEXIS 59497, at *30-31 n.8 (N.D. Cal. Apr. 25, 2013) ("[F]ailure to oppose a statute of limitations argument constitute[s] a waiver.").

b. Plaintiffs Fail to Allege That EPA Declined Any Request for Data

Similarly, Plaintiffs do not contest that FIFRA requires only that EPA make registration data available upon request, with specific limitations. *See* Mot. at 21. Plaintiffs fail to allege a single instance where EPA denied a data request, and instead merely repeat their conclusory allegation that there was a "lack of public data availability." Opp. to EPA at 16. This is insufficient to state a claim. *See, e.g.*, *Colony Cove Props., LLC v. City of Carson*, 640 F.3d 948, 957 (9th Cir. 2011) (conclusory allegations insufficient).

c. Plaintiffs Articulate No Potential Prejudice From the Lack of Additional EPA Notices

Plaintiffs do not deny that EPA issued 79 Federal Register notices over 15 years regarding EPA's clothianidin and thiamethoxam registration activities, and that Plaintiffs failed to comment on a single one. *See* Mot. at 19-20. Plaintiffs claim that prejudice from the alleged lack of additional notices can be presumed because the error is "procedural." *See* Opp. at 22. Plaintiffs ignore the controlling Supreme Court precedent holding that prejudice cannot be presumed, even from the lack of required notice, and that a plaintiff has "the burden of showing that an error is harmful." *Shinseki v. Sanders,* 556 U.S. 396, 409 (2009); *see also Molina v. Astrue*, 674 F.3d 1104, 1111 (9th Cir. 2012); *Tongass Conservation Soc'y v. U.S. Forest Serv.*, 455 F. App'x 774, 777 (9th Cir. 2011).

Based on cases predating *Shinseki*, Plaintiffs complain that Intervenors "grossly overstate Plaintiffs' obligation to show harm from EPA's violations."[16] Opp. at 23. All the cases cited by Plaintiffs involved the fundamentally different process of notice-and-comment rulemaking. *See* Opp. at 23-24.[17] FIFRA's "notice of application" serves a much more limited purpose. A "notice of application" issues months before EPA has arrived at any proposed decision, and FIFRA expressly provides that the underlying data and analysis are not made available for substantive public comment in response to such a notice. 7 U.S.C. § 136a(c)(2)(A) (data to be made available only *after* EPA issued its final decision). Given these fundamental differences, the cases cited by Plaintiffs are inapplicable, and no reduced burden to show prejudice is appropriate.[18]

In any case, regardless of the magnitude of Plaintiffs' burden, it is not zero. *Shinseki* held that *some* showing of prejudice is required, and that prejudice cannot be presumed merely because the alleged error is procedural. Plaintiffs offer no showing of prejudice whatsoever. They have failed to identify a single relevant fact or argument that might have been submitted if EPA had issued the additional notices, or to articulate how the outcome might have been affected. On the same facts, the Supreme Court found that this falls far short. *See Shinseki*, 556 U.S. at 413. Regardless of how high the bar, Plaintiffs have failed to clear it. Claims 3 and 4 should be dismissed.[19]

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[16] The one cited case issued after *Shinseki* involved a process equivalent to notice-and-comment rulemaking, and made no reference to *Shinseki* or to the prejudicial error rule codified in the APA. *See Nw. Res. Info. Ctr., Inc. v. Nw. Power & Conservation Council*, 730 F.3d 1008 (9th Cir. 2013).

[17] *See* 5 U.S.C. § 553(b)(3) (agency must publish "the terms or substance of the proposed rule or a description of the subjects and issues involved"); *Cal. Wilderness Coal. v. Dep't of Energy*, 631 F.3d 1072, 1090 & n.12 (9th Cir. 2011) (agency must publish for comment the data and methodology supporting the proposed rule).

[18] In a footnote, Plaintiffs mischaracterize Intervenors' argument regarding tolerance notices issued pursuant to the FFDCA by suggesting that these notices "cannot cure EPA's procedural violations under FIFRA." Opp. at 22 n.14. This misses the point. Plaintiffs do not deny that the FFDCA notices are inextricably linked to EPA's registration actions, and thus provided additional notice of those actions, or that Plaintiffs failed to submit any comments in response. Mot. at 17-20.

[19] Plaintiffs also assert that to apply the harmless error rule is "to condone" the error alleged. Opp. at 23-24. Plaintiffs' invitation to ignore settled law is wholly inappropriate, and overlooks the important policy interests served by the rule. *See Shinseki*, 556 U.S. at 407-08 (harmless error rule "prevent[s] courts from becoming 'impregnable citadels of technicality'") (citation omitted).

3. Plaintiffs' Conclusory Allegations That Unspecified Conditions of Registration Were Unfulfilled Are Insufficient (Claims 5-6)

In Claims 5 and 6, Plaintiffs generally allege that conditions of registration for unspecified clothianidin and thiamethoxam product registrations were not met and that EPA "unreasonably delayed" initiating cancellation proceedings. Am. Compl. ¶¶ 120-27. In their Opposition to EPA, Plaintiffs also contend that EPA "unlawfully with[held] the imposition of conditions with limited time frames" or "attach[ed] conditions with time frames but then allow[ed] them to go unsatisfied." Opp. to EPA at 18.[20] Plaintiffs' conclusory assertions fall far short of what is necessary to withstand a motion to dismiss. *See Hydrick v. Hunter*, 669 F.3d 937, 939-42 (9th Cir. 2012) (conclusory allegations insufficient).

a. Plaintiffs Conflate Conditions of Registration With Potential EPA Requests for Additional Data After Registration

According to Plaintiffs, the Complaint "identifies unsatisfied conditions — and thus missing information — associated with each" of the 81 conditional registrations listed in the Complaint's Appendices. Opp. to EPA at 19. In fact, the only specific condition Plaintiffs allege is that a "pollinator field study" was imposed as a condition of the initial registrations of both clothianidin and thiamethoxam, and Plaintiffs' claims regarding that condition are barred by the six-year limitations period. Mot. at 21. For the remainder of the conditional registrations listed in the Complaint, Plaintiffs allege that EPA identified seven thiamethoxam "data requirements" as part of the ongoing Registration Review process, and then conclude that the need for these additional data so many years after the initial registrations must mean that conditions of registration were not satisfied. *See* Am. Compl. ¶ 96 (citing Final Work Plan for Registration Review); Opp. to EPA at 20. For clothianidin, Plaintiffs similarly make clear that their allegations of unfulfilled conditions are "based on data gaps." Am. Compl. ¶ 94.

[20] Plaintiffs further contend that EPA violated FIFRA "by using vague and unenforceable condition language, without any identifiable deadline for satisfaction." Opp. to EPA at 21; *see also* Am. Compl. ¶¶ 122, 126 (alleging "impermissibly vague" conditions of registration that allowed more than a "reasonable" time for registrants to satisfy them). Plaintiffs point to only one such condition, requiring a registrant to submit or cite a study "no later than the time this study is required to be submitted or cited for current thiamethoxam registrations." Am. Compl. ¶¶ 92-93. This requirement is taken directly from the provisions of FIFRA that allow conditional registrations. *See* 7 U.S.C. § 136a(c)(7)(A), (B). Plaintiffs' challenge to this language is properly raised with Congress.

A "data gap" or any other determination by EPA that an existing registration requires additional data is legally distinct from a condition of registration. A condition of registration is a specific obligation imposed by EPA when a given registration is issued or amended requiring the registrant to submit a specific study or take other specified action by a certain date. 7 U.S.C. §§ 136a(c)(7)(A)-(C); 40 C.F.R. §§ 152.113-115. When EPA determines that additional data are needed to maintain a registration, this does *not* mean that EPA must or will impose a condition of registration. Instead, FIFRA provides the separate and distinct "data call-in" process to allow EPA to require additional data to support existing registrations, a process with its own deadlines and consequences for inaction. 7 U.S.C. § 136a(c)(2)(B).

Contrary to the impression Plaintiffs seek to create, EPA routinely requires additional data to support the continued registration of existing products. A key purpose of Registration Review, required every 15 years for every active ingredient, is to allow EPA to identify any additional data necessary to confirm whether the products containing the active ingredient continue to meet the stringent standard for registration in light of modern testing standards and evolving scientific understanding of potential health and environmental risks. *See, e.g.*, 7 U.S.C. § 136a(g); 40 C.F.R. §§ 155.58(b)(3) (EPA may request additional data at time of Registration Review decision), 155.48 (data call-ins as part of Registration Review process), 155.40(c)(2) (same), 155.53(b)(1)-(2) (same).

Taken as true, Plaintiffs' allegations that EPA reviewers have identified a potential need for additional data fall far short of demonstrating that a condition of registration was imposed (or should have been imposed) on any particular registration, or that a registrant failed to meet any specific condition of registration by a particular deadline. *See, e.g.*, *Somers v. Apple, Inc.*, 729 F.3d 953, 960 (9th Cir. 2013) ("Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief.") (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). Claims 5 and 6 should be dismissed.

b. Extensive Information on Conditions Was Available to Plaintiffs

Plaintiffs contend they pled "without further specificity" because the "facts are peculiarly within the control of" EPA. Opp. at 22. But EPA registration decisions and the conditions imposed on each registration are available from EPA's Pesticide Product Label System, a public database that Plaintiffs

cite as the source for the Appendices to their Complaint.[21] *See* Am. Compl., App. A-B.[22] Plaintiffs' failure to allege any actionable claim based on an unfulfilled condition of registration cannot be attributed to a lack of access to information. *See, e.g.*, *Colony Cove Props.*, 640 F.3d at 957 (no assumption of truthfulness for conclusory allegations contradicted by documents referenced in the complaint).

4. Plaintiffs' Challenges to EPA's Unconditional Registration Decisions Are Legally Baseless (Claims 7-8)

Plaintiffs make clear that Claims 7 and 8 are based entirely on the notion that any unconditional registration of a product containing clothianidin or thiamethoxam was arbitrary and capricious because other products containing the same active ingredients remain conditionally registered, with outstanding data requirements to be filled. *See* Opp. to EPA at 23-25; Opp. at 24-25. Plaintiffs' conclusory allegations fail as a matter of law. Simply put, nothing in FIFRA provides that all products with the same active ingredient must require the same data.

For example, products containing clothianidin have approved uses limited to indoor application, such as control of bedbugs. *See, e.g.*, Am. Compl., App. A at 5. EPA may impose conditions on such indoor product registrations — such as an indoor exposure study — that would not apply to an unrelated, purely outdoor use on crops. Plaintiffs' theory that EPA must impose the same conditions on all products simply because they contain the same active ingredient is nothing more than a legally incorrect conclusory allegation and fails to state a claim upon which relief may be granted. *Johnson v. Riverside Healthcare Sys.*, 534 F.3d 1116, 1121-22 (9th Cir. 2008) (dismissal is appropriate where the complaint fails to state a cognizable legal theory or sufficient facts to support one).

5. EPA's Continuing Authority Under FIFRA Is Not an "Action" That Triggers ESA Consultation (Claims 13-14)

Finally, Plaintiffs mistakenly assert that EPA's "continuing authority over clothianidin and thiamethoxam is affirmative agency action triggering the duty to consult." Opp. to EPA at 30; Am. Compl. ¶¶ 160, 165. That theory was correctly rejected in *CBD v. EPA*, 2013 U.S. Dist. LEXIS 57436

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[21] *Available at* http://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1 (last visited Dec. 10, 2013).

[22] Registration decisions and conditions are also available in an electronic reading room, at http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct=SR;D=EPA-HQ-OPP-2007-1024 (last visited Dec. 5, 2013).

(N.D. Cal. Apr. 22, 2013). Plaintiffs seek to distinguish *CBD v. EPA* because it concerned 382 pesticides rather than two, and did not involve FIFRA claims. These arguments are unavailing. Regardless of the number of pesticides at issue, Ninth Circuit precedent makes clear that EPA's "continuing authority" simply does not constitute affirmative agency action that triggers an ESA consultation duty and is not a substitute for identifying specific agency action(s) allegedly requiring consultation. *CBD v. EPA*, 2013 U.S. Dist. LEXIS 57436, at *29-32 (citing *Karuk Tribe v. U.S. Forest Serv.*, 681 F.3d 1006, 1021 (9th Cir. 2012) (*en banc*)).

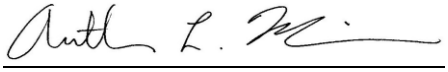
Plaintiffs list over 100 EPA registration activities without specific allegations of harm to species from each. Am. Compl. ¶¶ 159-160, 164-65.[23] Plaintiffs point to other "facts" they have alleged, such as harm to wildlife on "over 100 million cropland and surrounding acres" and "at least fifteen" protected pollinators that allegedly are affected. Opp. to EPA at 25-26. But these wholesale and conclusory allegations, taken as true, are insufficient to show that a specific EPA action within the scope of this Court's jurisdiction has harmed a listed species in which the Plaintiffs have an interest. Since "clear identification of specific affirmative act or acts that trigger the duty to consult is of the utmost importance," *CBD v. EPA*, 2013 U.S. Dist. LEXIS 169015, at *19, Claims 13-14 should be dismissed.

III. CONCLUSION

For the foregoing reasons, Claims 3-9, 13-14, and parts of Claim 1 should be dismissed for lack of jurisdiction, or alternatively for failure to state a claim.

Dated: December 10, 2013

Respectfully submitted,

By: 

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[23] This deficiency also underscores Plaintiffs' failure to demonstrate that their ESA claims are timely. Plaintiffs provide no response to Intervenors' argument that Plaintiffs' ESA claims are time barred. *See* Mot. at 24-25; *see also Ramirez v. Ghilotti Bros.*, 2013 U.S. Dist. LEXIS 59497, at *30-31 n.8 ("[F]ailure to oppose a statute of limitations argument constitute[s] a waiver.").

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